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Report Highlights:
This report provides the latest updates of Vietnam's regulatory processes relevant to the management of biosafety. The Vietnam National Assembly ratified the Biodiversity Law in November 2008, with an effective date of July 1, 2009. Chapter 5, part 3 of this law addresses management of Genetically Modified Organisms and specimens. In order to implement the Biodiversity Law, Vietnam has drafted a Biosafety Decree, which will be submitted for government approval in September 2009. Both MARD Regulations for field trials of GM crops and VFA's regulations on the management of GM foods that were reported to WTO in early 2008 have not yet been approved. MARD anticipates getting approval to conduct field trials by the end of 2009.

Section I. Executive Summary:

Vietnam has drafted a new Biosafety Decree to replace the Biosafety Regulations (Decree 212) approved in 2005. (VM5062) The Biosafety Decree will provide the legal framework for management of Genetically Modified (GM) organisms and their products and it is expected to be submitted for government approval in September, 2009. Vietnam currently has no restrictions on the importation of GM products and imports considerable amounts of biotech cotton, soybeans, soybean meal and corn from the United States and other countries.

Production of GM crops and trade in GM seeds are still not yet allowed in Vietnam as the biotech regulations to allow these have yet to be approved. The Ministry of Agriculture and Rural Development (MARD) has previously reported its draft regulations for biosafety management of genetically modified crops to the WTO and received comments from

various countries, including the United States. These regulations, when approved, will allow field trials of GM crops and ultimately commercialization of GM crops after a successful trial period. Notwithstanding the absence of approved biotech regulations, reports are that much of the cotton being grown in Vietnam is GM.

MARD hopes to begin field trials as soon as possible and anticipates getting approval for its regulations by the end of 2009. This is, however, contingent on the approval of the new draft Biosafety Decree. Like MARD, the Vietnam Food Administration (VFA) in the Ministry of Health, which has regulatory control for the import, export and trade of GM foods, must also await approval of the new Biosafety Decree to have its regulations which were reported to WTO in early 2008 approved. Only after all these regulations have been approved will the status quo for biotech products in Vietnam be altered.

A possible troubling element for U.S. trade in the latest draft of the Biosafety Decree is a requirement for mandatory labeling. The threshold is set at 5%, so products with a greater percentage of materials derived from GM organisms would need to be labeled. Importers of GM materials for feed use would need to register them with MARD, while GM food products would be registered with VFA. MARD is to develop a list of GM products that may be used for feed and VFA will indicate what GM products will be allowed for use as food.

Section II. Biotechnology Trade and Production:

Vietnam remains keen to produce genetically modified (GM) crops, particularly soybeans, corn and cotton, in order to reduce its dependence on imports of these key commodities, used as inputs in Vietnam's large feed and textile industries. Vietnam ratified the Biosafety Regulations (VM5062) that provide the framework for research, production and trade of GM products in 2005, but the implementing guidelines that would allow GM crops to be commercially produced and traded have not yet been approved. Vietnam is currently working on a new biosafety decree to replace the 2005 biosafety regulations. The new decree will include requirements and conditions or criteria for import, transport and storage of GM organisms and products.

The Ministry of Agriculture and Rural Development (MARD) previously reported draft regulations for field testing and biosafety management of genetically modified crops (VM8005) to WTO and received comments from various countries including the United States. MARD planned to approve these regulations in 2008, but given the new biosafety decree being drafted, new or revised implementing regulations may be required. Scientists and policymakers are nonetheless anxious to conduct field trials so that Vietnam may commercialize GM production and reduce dependency on imports. A recent survey by a biotechnology center in the corn growing provinces of Dong Nai, An Giang, Dac Lac (in the South), Son La, Thanh Hoa and Nghe An (in the North) reported that more than 70% of farmers interviewed said they were willing to grow GM corn for its advantages (lower production cost, lower pesticide use and labor application costs) over hybrid and traditional corn varieties. These farmers will not, however, be able to grow GM corn until MARD approves regulations allowing field testing and commercialization of GM crops.

The Vietnam Food Administration (VFA) in the Ministry of Health, like MARD, has reported its draft regulations for the 'Management of the Safety and Hygiene of Foods Originated from Gene-Modified Organisms' to WTO in 2008 and received comments from the United States and other countries. These draft regulations, which cover the import, export and trade of GM foods may also need to be revised to conform to the new Biosafety Decree before they can be approved.

Vietnam currently imports large quantities of agricultural biotech commodities including cotton, corn, soybeans and soybean meal. Vietnam's cotton lint imports in CY 2008 were 291 thousand metric tons, an increase of 21% over the previous market year. The United States is the leading supplier of cotton to Vietnam (VM9032). In 2008, Vietnam also imported 610 thousand metric of corn for animal feed from several countries, including Argentina, Brazil and the United States, which are large producers of Bt corn. (VM9025) Vietnam's soybean meal imports from Argentina, the United States and Brazil were an estimated 2.4 million metric tons in 2008, and much of this would have been biotech soybean meal. (VM9033)

Section IV. Biotechnology Policy:

Vietnam's Biodiversity Law effective July 1, 2009

On November 13, 2008, Vietnam's National Assembly ratified the Biodiversity Law that became effective on July 1, 2009. There are a total of eight chapters, entitled as follows:

Chapter 1: General Provisions
Chapter 2: Biodiversity reservation planning
Chapter 3: Conservation and sustainable development of natural ecosystems
Chapter 4: Conservation and sustainable development of biological organisms
ıservation and preservation of heritage resources
rnational cooperation on biodiversity
:hanism and resources for biodiversity conservation and sustainable development.
ılementation

Part 3 of Chapter 5 focuses on risk management of genetically modified organisms and specimens' impact on biodiversity. This section provides general requirements for risk assessment, risk management and biosafety certification for research, release, import or export of genetically modified organisms and genetically modified specimens. There are also requirements for organizations or individuals who perform research/release into the environment or import/export of genetically modified organism or specimens to provide information on the level of risk and the measures for risk management. The Ministry of Natural Resources and Environment (MONRE) will maintain a database of genetically modified organisms and genetically modified specimens relevant to biodiversity.

Biosafety Decree for the Management of Genetically Modified Organisms and Products expected to be approved by the end of 2009

In order to implement Chapter 5, Part 3 of the Biodiversity Law (VM5062) MONRE and other relevant ministries have drafted a Biosafety Decree for the management of genetically modified organisms and products derived from genetically modified (GM) organisms. This Decree will provide the legal framework for research and trade of GM organisms and GM products. A technical drafting team comprised of representatives from several ministries including MONRE, the Ministry of Agriculture and Rural Development, (MARD) the Ministry of Industry and Trade, (MOIT) the Ministry of Justice, (MOJ) the Ministry of Health, (MOH) and Vietnam Customs General Department was formed in early 2009. The drafting team has been meeting regularly and hopes to submit the final draft of the Decree to the Government for approval by September 2009.

The Biosafety Decree will regulate the management of research, technology development, testing, production, trading and use, imports/exports, storage, transportation and risk assessment/management of GM organisms and their products. This decree will not cover GM organisms used for pharmaceutical purposes. Draft six, the latest draft, includes provision for the formation of a National Council of Biosafety and an Office of Biosafety. MONRE will head the Council which will have members from several ministries including MARD, MOH and MOIT.

The latest draft of the Decree has provisions for risk assessment, field trials and the ultimate biosafety certificate. It also outlines the responsibility of MARD, MOH and MONRE, the primary ministries to implement it. One element of particular concern to Post and U.S. trade is the requirement for mandatory labeling in the latest draft. The threshold level is set at 5%. Thus, products containing more than 5% GMOs will have to be labeled. The Ministry of Science and Technology (MOST) will be responsible for providing guidelines on labeling of GM products.

The latest draft of the Decree has 8 chapters and three appendices entitled:

Chapter 1: General Provisions
Chapter 2: Risk Assessment and Risk Management
Chapter 3: Scientific Research and Technology Development
Chapter 4: Trials and testing for Risk Assessment of GM Organisms
Chapter 5: Biosafety Certification
Chapter 6: Production and trade of GMOs and GM Products
Chapter 7: Information on GMOs and GM Products

Chapter 8: Implementation Provision

equired documents as stipulated in Article 36 of the Cartagena Protocol
ossier requesting risk assessment for field trial of GMOs
Appendix 3: Risk Assessment Report

Post will provide further update on the Decree as it becomes available.

Vietnam ratified the "National Action Plan on Biological Diversity to 2010 and the Strategy for implementation of the Convention on Biological Diversity and the Cartagena Protocol on Biodiversity to 2020" (see VM7059)

On May 31, 2007, Prime Minister Nguyen Tan Dung signed Decree No. 79/2007/QD-TTg to promulgate the National Action Plan for implementation of the Convention on Biodiversity and the Cartagena Protocol, with targets for 2010 and 2020. The Action Plan covers all aspects of biological diversity including management of genetically modified organisms (GMO) and GM products. Under the Plan, Vietnam's targets set for 2010 include conducting risk assessments, labeling, and monitoring and inspecting of all GM organisms and products marketed in Vietnam. It is doubtful these objectives can be met within the prescribed timeframe, particularly given the pace of progress on the regulations for commercialization. Moreover, these proposed activities assume a capacity of trained personnel and research facilities, which are still lacking in Vietnam. Strict implementation of the Plan would, in fact, seriously impact the animal feed and livestock industries, not to mention the fishery and textile industries, two major export income earners for Vietnam.

A number of objectives to be enacted by 2020 are also outlined in the Action Plan. Vietnam aims to strengthen the regulatory framework to manage GMOs and GM products so as to ensure the safety of human health and the environment, while also maintaining biological diversity. State of the Art laboratory facilities and the most up-to-date research methods and information systems are also projected as well as a database on the management of biodiversity and biosafety. The Ministry of Environment and Natural Resources (MONRE) will take the lead on the implementation of the Plan. Several other ministries will participate in the implementation of the Plan, according to their area of responsibility; namely, the Ministries of Agriculture and Rural Development (MARD), Science and Technology (MOST), Education and Training (MOET), Culture and Information, Industry and Trade (MOIT), Finance (MOF) and the Ministry of Planning and Investment. Although the Plan became effective on July 7, 2007, thus far no Ministry has yet completed their implementing regulations for this Plan.

Vietnam unlikely to achieve its ambitious Biotechnology Plan by 2010 and 2020

Given that Vietnam still has no approved biotech implementing guidelines, it is doubtful that Vietnam can meet the targets set for 2010 or 2020. The Ministry of Agriculture and Rural Development's (MARD) regulations to allow field trials of GM crops have yet to be approved. And, even assuming they were to be approved by the end of 2009, field trails are expected to run for at least two years before any GM crops would be released for commercial production. Furthermore, the draft of the regulations call for certification of the tested crops (corn, soybean) as safe for human consumption by the Vietnam Food Administration (VFA) in the Ministry of Health once MARD has completed its field trials and analysis. VFA's biotech regulations have also not yet been approved and given these two tiers of approval, it is highly doubtful that commercialization of locally grown GM crops will be in force by 2010 as planned. Moreover, with the new Biosafety Decree yet to be approved, all biotech field trial and planting schedules will be delayed.

The same can be said for the goals of Decree 11/2006/ND-TTg for "Key Programs and Application of Biotechnology in Agriculture to 2020" that was signed by the Prime Minister on January 12, 2006. Under this plan, Vietnam expects to create new plant varieties, animal breeds and biotech products through application of biotechnology, so as to enhance the competitiveness of Vietnam's agricultural and fishery products, both domestically and internationally. A target annual investment of about VND100 billion (about $6.3 million) in biotech programs is set for these programs. MARD is the lead agency for these programs and must coordinate the work of the Ministry of Science and Technology, the Ministry of Industry, the Ministry of Planning and Investment and local authorities. Vietnam expects to develop a variety of biotech seeds, including cotton, maize and soybeans, which would be commercially released by 2010, with biotech crop varieties accounting for about 70% of total crop production by 2020.

Vietnam's Labeling Regulation

The newly approved Biodiversity Law has no specific labeling requirement for GM organisms or their products. It does state, however, that individuals or organizations which conduct research, release into the environment or import/export GM organisms or specimens must publish information on the risk level and measures for managing risk. The most recent draft of Vietnam's new Biosafety Decree contains a requirement for mandatory labeling of products with more than 5% of materials derived from GM organisms. Vietnam is also upgrading its Food Safety Ordinance, approved in 2003, (VM3014) into a Food Safety Law. This law, which will be debated by the National Assembly in Fall 2009, also contains requirements for labeling of GM food.

VFA, the regulatory body within the Ministry of Health with oversight of food for human consumption, has drafted new labeling regulations for packaged foods. These draft regulations stipulate that labels (or sub-labels) are required for foods containing more than 5% of materials derived from gene technology and must clearly state, in Vietnamese, the phrase "using gene technology." (VM8020) Labeling of GM foods will be costly for consumers and traders and could also lead to misunderstanding about the safety of GM foods. VFA argues, however, that labeling of GM food merely provides the consumers with full information about the product so that he/she can make a more-informed choice, and it should not harm the market for GM food. VFA's stance on labeling is echoed in the Biosafety regulations approved in 2005 (VM5062); Vietnam Food Ordinance (VM3014); the Goods Labeling Decree in 2006 (VM7037) and the National Action Plan (VM 7059). VFA's labeling regulations have not been notified to WTO nor have they been approved.

Intellectual Property Rights Law

According to an IPR expert in the Ministry of Agriculture and Rural Development, (MARD) the Vietnam Intellectual Property Rights Law approved in 2005 can be applied to GM crops approved for cultivation in Vietnam. In November 2005, the Vietnam National Assembly passed a comprehensive Intellectual Property Rights (IPR) law. Part four of the law covers IPR for plant varieties and follows closely the International Union for the Protection of New Varieties of Plants (UPOV) guidelines. Vietnam became a member of UPOV in December 2006.

The Ministry of Agriculture and Rural Development (MARD) has the lead on Intellectual Property Rights for plant varieties and was responsible for drafting the law and implementing regulations. MARD established Vietnam's Plant Variety Protection Office (PVPO) under the Department of Crop Production (DCP) in 2004. PVPO actively participated in drafting Vietnam's Intellectual Property Rights for plant varieties and the procedures for Vietnam to become a member of the UPOV.

On September 22, 2006, Prime Minister Nguyen Tan Dung signed Decree No. 04/2006/ND-CP, which provides detailed guidelines for implementation of the chapters on Plant Variety Rights in the Intellectual Property Law. The Decree offers guidance on the execution of articles on Plant Variety Rights, including State management of Plant Variety Protection; the order and procedures for defining plant variety rights; rights and obligations of plant variety certificate holders and plant variety creators; and the transfer or assignment of rights' licenses for protected varieties.

Information relating to the PVPO's operations can be found, in both English and Vietnamese at: http://pvpo.mard.gov.vn.

Section V. Marketing:

There is no active anti-biotech campaign or groups in Vietnam to sway public opinion regarding adoption of biotechnology. As noted earlier, Vietnam currently imports huge quantities of GM soybeans, soybean meal, corn and cotton as inputs for its export industries. The new Biosafety Decree has elements, however, that could be burdensome or costly to the trade. In particular, requirements for mandatory labeling could deter exports to Vietnam or add layers of bureaucracy, not to mention added costs for segregation and testing of commodities.

Vietnam has several research institutes, including the Institute of Biotechnology, the Vietnam Agricultural Science Institute, the Agricultural Genetics Institute and the Institute of Tropical Biology engaged in research on biotech crops in the laboratory. Biotech research is being done on rice, sweet potatoes, papaya, cotton, maize and flowers since 2006. Scientists anxiously await approval of MARD's regulations so that they may proceed with field trials. Several MARD

research institutes are also working on proposals for field testing of soybeans, corn and cotton in preparation for field trials as soon as MARD's biotech regulations are approved. Scientists in Vietnam are optimistic on having Vietnam first ever GM crops released to commercial production by 2015.

Vietnam faces a number of challenges in the development of biotechnology, not least of which is the shortage of skilled or experienced scientists and personnel in the biotechnology field. Reportedly scientists of leading agricultural research institutes are bemoaning the lack of such skilled personnel to fully or effectively utilize improved equipment and laboratories at these institutes. Vietnamese scientists who receive advanced training overseas tend to leave public institutes for the private sector where salaries and working conditions are more attractive. Vietnam, nevertheless, continue to work to improve capacity in biotechnology and the government has plans to send up to 300 students abroad for Masters and doctoral degrees in biotechnology-related field over the next 10 years.

Section VI. Capacity Building and Outreach:

From August 2008 to the present, FAS/Vietnam made considerable effort to support Vietnam and build capacity in biotechnology. Post, in partnership with FAS/W supported a variety of workshops and activities to increase the knowledge base of regulators, scientists and the public about biotechnology in addition to supporting their attendance at international meetings in the field.

Some of Posts' biotech activities during this period:

- May 28-29, 2009, with support from a TIRF grant, implemented a targeted workshop on "Biotech Labeling: Considerations and Impacts" in Ho Chi Minh City for the benefit of the drafting team of the Biosafety Decree. This workshop which closely examined the cost and systems needs of biotech labeling also provided a forum for regulators and the industry to both learn from the international experts in the field as well as exchange ideas and concerns. Well over 80 participants from MONRE, MARD, MOH, MOST, research institutions, seed companies, feed mills and food traders benefited from experiences and information shared by experts from India, Australia, European Union, Japan and the United States. Members of the drafting team also had an opportunity to present elements of the Biosafety Decree and get feedback from both the experts and industry members.

- March 20, 2009, using TIRF funding, implement a half-day workshop on biotech labeling considerations in Hanoi for the benefit of the Biosafety Decree drafting team, with speakers from CropLife Asia and Cyngenta. This workshop, which was a precursor to the one in HCMC, also included members of the international community such as FAO, STAR, (a USAID funded project) and U.S. Embassy, as well as Vietnam's Codex Office and other relevant Vietnam government officials.

- supported two senior officers from MARD and MONRE to participate in the APEC High Level Policy Dialogue on Low Level Presence and Agricultural Biotechnology held in Singapore from February 16-21, 2009.

- November 20, 2008, supported speakers from U.S. EPA to attend an ASEAN Regional workshop on Information Sharing for Risk assessment and Risk management of LMOs/GMOs in ASEAN countries that was held in Dalat, Vietnam and hosted by Vietnam's Environmental Protection Administration, VEPA.

- November 10-12, 2008, provided funding for ISAAA to conduct a workshop on how to Conduct Risk Assessments for GM Food Safety Approval in Ha Long Bay, Vietnam. This workshop was targeted at officials from the Vietnam Food Administration (VFA) which is the agency with responsibility for regulating food safety and has jurisdiction over both domestic and imported foods.

- funded two senior scientists from MARD and Ho Chi Minh Biotechnology Center under the Cochran Fellowship Program to attend the International Short Course Training on Agricultural Biotechnology at Michigan State University, from September 7-19, 2008

- September 10-20, 2008, provided funding for a Vietnamese official to attend the High Level Policy Dialog on

Biotechnology (HLPDAB) steering committee meeting and consultative forum on crop acceptance in Singapore.